

### **REMARKS**

In an office action mailed May 13, 2003, the Examiner has rejected claims 29 and 33-45 under 35 U.S.C. §112, claims 29 and 33-45 under 35 U.S.C. §102(e) and claims 44 and 45 under U.S.C. §103. In response thereto, Applicants submit the above amendments and the following remarks.

By this amendment, claims 29, and 33-45 have been cancelled and new claims 46-56 have been added. Accordingly, claims 46-56 are currently pending in the application.

Applicants extend their gratitude to Examiner Mosher for taking the time to engage in a telephone discussion with Applicants representative on September 10, 2003. Examiner Mosher's generosity of her time and knowledge is greatly appreciated.

### **Support For New Claims**

New claims 46-56 correspond to cancelled claims 29 and 33-43. New claim 46 now further recites a method for inducing or stimulating a T-helper cell response in a human or animal against at least one antigen, while avoiding repeated exposure of vector proteins or vector encoded proteins. Support for claim 57 can be found in the application on page 4, lines 18-22.

### **Rejections Under §112**

In the office action, claims 29 and 33-45 have been rejected under §112, second paragraph as being indefinite with regards to the recitation of "a first vaccine composition comprising said antigen and a first vector..." According to the Examiner, the claim language is confusing. At the Examiner's suggestion, claim 29 has been cancelled and new claim 46 has been added. Claim 46 recites "comprising a first vector encoding said antigen...", etc.

The Examiner also pointed out some errors concerning dependency and antecedent basis in claims 33 and 41-43. These claims have been cancelled and the new claims do not contain the pointed to errors.

Accordingly, Applicants respectfully request that the rejections under §112 be reconsidered and withdrawn.

#### **Rejections Under §102**

In the office action, claim 44 continues to be rejected under §102(e) as being anticipated by U.S. Patent No. 6,210,663 to Ertl. In the interest of moving this application towards allowance, claim 44 has been cancelled, reserving the right re-introduce the subject matter therein at a later date or in a continuation application.

Accordingly, Applicants respectfully submit that the rejection of claim 44 under §102(e) based on Ertl has been rendered moot.

Claims 29 and 33-43 have been rejected under §102(e) as being anticipated by U.S. Patent No. 6,511,845 to Davis et al. In support of the rejection, the Examiner points to Treatment Regimens 1 and 3 in Davis, where allegedly three different adenoviral vectors were administered sequentially for the purpose of inducing an immune response to a lentivirus

New claim 57 recites a method for inducing or stimulating a T-helper cell response in a human or animal against at least one antigen, while avoiding repeated exposure of vector proteins or vector encoded proteins.

The method is accomplished by sequentially administering three vaccine compositions that comprise an antigen and a vector, wherein the vectors are different from one another. Applicants have discovered that the use of three different vectors, avoids repeated exposure of vector proteins or vector encoded proteins.

Avoiding repeated exposure of vector proteins or vector encoded proteins is desired because, for instance, the mounting of an immune response against a vector protein or vector encoded protein creates competition for immune resources such as immune cells or cytokines, thereby lowering the desired response against the vaccination proteins (e.g. antigens).

Figures 1A & B in the application compares immune response when using the same vector (A) and when using different vectors (B). The response in (A) shows that use of the same vector

results in an increase in immune response to the vector while the immune response to the antigen is lower in comparison to the immune response to the antigen in (B).

In Davis, three serotypes of the same virus (adenovirus) are used as the vectors in the immunization protocol disclosed. Davis' use of three serotypes of adenovirus results in repeated exposure of vector proteins or vector encoded proteins which serve to boost the immune response to the so-called "common antigens." As a result, the desired response against the vaccination proteins is lowered. It is this very problem that is addressed by the present invention.

The new claims recite a method for inducing or stimulating a T-helper cell response in a human or animal against at least one antigen, while avoiding repeated exposure of vector proteins or vector encoded proteins. The method is accomplished by sequentially administering three vaccine compositions that comprise an antigen and a vector, wherein the vectors are different from one another.

Since Davis does not disclose a method for inducing or stimulating a T-helper cell response in a human or animal against at least one antigen, while avoiding repeated exposure of vector proteins or vector encoded proteins, by sequentially administering three vaccine compositions that comprise an antigen and a vector, wherein the vectors are different from one another, Davis cannot be found to anticipate the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under §102 based on Davis..

**Rejections Under §103**

Claims 44 and 45 have been rejected under §103 as obvious over Davies et al and Chamberlain WO 97/06632.

As mentioned above, in the interest of moving this application towards allowance, claims 44 and 45 has been cancelled, reserving the right re-introduce the subject matter therein at a later date or in a continuation application.

Accordingly, applicants respectfully submit that the rejection of claims 44 and 45 under §103 based on Davies et al or Chamberlain WO 97/06632 has been rendered moot.

In light of the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance. If the Examiner believes a telephone discussion with the Applicant's representative would be of assistance, she is invited to contact the undersigned at her convenience.

Respectfully submitted,

Application No. 09/890,379  
Filing Date: July 27, 2001  
Docket No.: 294-105 PCT/US  
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**Response to Office Action of May 13, 2003**

A handwritten signature in black ink, appearing to read 'L. Emr', is positioned above a horizontal line.

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